

**RECEIVED**  
**CENTRAL FAX CENTER**

**MAR 18 2008**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

First Named Applicant: Walker	)	Art Unit: 3763
	)	
Serial No.: 09/939,239	)	Examiner: Desanto
	)	
Filed: August 24, 2001	)	001/017 (1-3) USA
	)	
	)	March 18, 2008
	)	750 B STREET, Suite 3120
	)	San Diego, CA 92101
	)	

**SUPPLEMENTAL APPEAL BRIEF**

Commissioner of Patents and Trademarks  
 Washington, DC 20231

Dear Sir:

This brief is submitted in response to the Notice of Non-Compliant Brief dated March 18, 2008, alleging that the Supplemental Appeal Brief filed over three years ago (not a typo) fails to include a heading for each ground of rejection discussed in Section 7. Appellant will restrain itself from giddiness at this sudden spasm of diligence on the part of the PTO, however, given that, while representing a commendable straining out of ministerial gnats, it nonetheless arrives *after* the belated Answer and a Reply thereto.

**Table of Contents**

<u>Section</u>	<u>Title</u>	<u>Page</u>
(1)	Real Party in Interest.....	2
(2)	Related Appeals/Interferences.....	2
(3)	Status of Claims.....	2
(4)	Status of Amendments.....	2
(5)	Concise Explanation of Subject Matter in Each Independent Claim.	2
(6)	Grounds of Rejection to be Reviewed.....	3
(7)	Argument.....	4
App.A Appealed Claims		
App.B Evidence Appendix		
App.C Related Proceedings Appendix		

1156017.AP1

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 2

RECEIVED  
CENTRAL FAX CENTER

PATENT  
Filed: August 24, 2001

MAR 18 2008

(1) **Real Party in Interest**

The real party in interest is Alsius Corp.

(2) **Related Appeals/Interferences**

No other appeals or interferences exist which relate to the present application or appeal.

(3) **Status of Claims**

Claims 5-8 and 22-34 are pending and finally rejected, Claim 38 (referred to by the Examiner as Claim 39) has been restricted out, and the remaining claims have been cancelled. All rejections of all claims are subject to this appeal.

(4) **Status of Amendments**

No amendments are outstanding.

(5) **Concise Explanation of Subject Matter in Each Independent Claim, with Page and Figure Nos.**

As an initial matter, it is noted that according to the Patent Office, the concise explanations under this section are for Board convenience, and do not supersede what the claims actually state, 69 Fed. Reg. 155 (August 2004), see page 49976. Accordingly, nothing in this Section should be construed as an estoppel that limits the actual claim language.

Claim 5 recites a central venous line catheter (reference numeral 20, page 7, first paragraph of detailed description, Figure 1) having at least one substantially elongate structure (id. and page 8, second paragraph

1156-017.APJ

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 3

PATENT  
Filed: August 24, 2001

and Figures 2-5) configured for establishing central venous access. The structure has a proximal portion and a distal portion and defines at least a first lumen (e.g., 32, Figures 3 and 4, page 10, first paragraph) in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element (24, Figures 1-4, page 8 starting with last four lines) extending at least along the distal portion and adapted to effect heat exchange with the central venous system. The catheter is manufactured by flushing the first lumen from its distal portion to its proximal portion with sterile saline.

The page and figure references above are incorporated into this paragraph. In Claim 22, a venous line catheter system (10, figure 1, pages 7-8) has a catheter having at least one substantially elongate structure configured for establishing central venous access. The structure has a proximal portion and a distal portion and defines at least a first lumen in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element extending at least along the distal portion adapted to effect heat exchange with the central venous system. Unlike the invention of Claim 5, in Claim 22 a pump (in the module 50, figure 1, page 12 at bottom) feeds a heating/cooling agent at a flow rate in a range of 150 - 450 milliliters per minute through the heat exchange element (original Claim 22).

(6) Grounds of Rejection to be Reviewed on Appeal

(a) Claims 5-8 have been rejected under 35 U.S.C. §102 as being anticipated by Williams et al. (USPN 4,941,475).

(b) Claims 5-8 have been rejected under 35 U.S.C. §102 as being anticipated by Bresnahan et al. (USPN 6,117,105).

1156-017.AP1

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 4

PATENT  
Filed: August 24, 2001

(c) Claims 5-8, 22-27, and 31-34 have been rejected under 35 U.S.C. §103 as being unpatentable over Williams et al. in view of Loubser (USPN 6,110,139).

(d) Claims 5-8 and 22-34 have been rejected under 35 U.S.C. §103 as being unpatentable over Bresnahan et al. in view of Loubser.

(7) **Argument**

**Anticipation Rejection of Claims 5-8 using Williams et al.**

Claims 5-8 have been rejected under 35 U.S.C. §102 as being anticipated by both Williams et al. and Bresnahan et al. It is noted that the citation to the "entire reference" for each of the above-mentioned references in support of the rejections renders analysis of what the examiner is thinking problematic, and in any case is contrary to the guidance of MPEP §706.02(j) (the Examiner should set forth (1) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate...)

The allegation that Williams et al. is a "venous line catheter" is contrary to MPEP §2111.01 (terms must be construed as the skilled artisan construes them), because Williams et al. is placed in the heart to measure cardiac output, and no evidence exists of record that the skilled artisan regards heart-dwelling cardiac output measuring catheters as "venous lines". This observation previously has elicited the retort that "any catheter has the ability to be used as a venous catheter". In and of itself, that response merits reversal. It is facially wrong. Any catheter CANNOT be used as central venous line catheter, nor would the skilled artisan

1136-017.API

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 5

PATENT  
Filed: August 24, 2001

(a doctor) confuse a cardiac output catheter such as the one disclosed in Williams et al. (which, when positioned, must have its operative portion in the arterial system, not the venous system, in order to work) with a central line. It is legal error to impute such faulty education in catheter types to the skilled artisan. Simply put, Claim 5 requires a structure - a central venous line catheter - that Williams et al. manifestly would not be considered to be by the skilled artisan, see MPEP §2111.01.

Furthermore, the anticipation rejections of Claim 5 are contrary to MPEP §2131 and consequently must be withdrawn because they fail to mention the limitation of Claim 5 that the catheter is manufactured by flushing the first lumen (as recited, this is an infusion lumen since it terminates at the exterior of the catheter) from its distal portion to its proximal portion with sterile saline. This is a structural limitation, since it means that residual salt remains in the lumen. This previously has been met with the argument that "applicant is reading limitations from the specification into the claims", because "there is no limitation that describes salt being left on the catheter".

**Anticipation Rejections of Claims 5-8 using Bresnahan et al.**

The allegation that Bresnahan et al. is a central venous line catheter is even further off base. Bresnahan et al. is placed in the *arterial* system during bypass surgery for perfusion of substances such as heart-stopping drugs. Is it seriously the examiner's position that the skilled artisan would think that Bresnahan et al. is a central venous catheter?

Note that "central venous catheter" is no mere intended use. Claim 5 ties this recitation to specific structure, i.e., an elongate structure configured for establishing central venous access.

1136-017.API

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 6

PATENT  
Filed: August 24, 2001

Furthermore, the anticipation rejections of Claim 5 are contrary to MPEP §2131 and consequently must be withdrawn because they fail to mention the limitation of Claim 5 that the catheter is manufactured by flushing the first lumen (as recited, this is an infusion lumen since it terminates at the exterior of the catheter) from its distal portion to its proximal portion with sterile saline. This is a structural limitation, since it means that residual salt remains in the lumen. This previously has been met with the argument that "applicant is reading limitations from the specification into the claims", because "there is no limitation that describes salt being left on the catheter".

It should be noted that Appellant is not here relying on a bare product-by-process limitation. Rather, anything flushed with salt cannot help but have at least some amount of residual salt on it, whether residual salt is claimed or not. In effect, the product-by-process limitation cannot but require a structure - a catheter with residual salt in a lumen - that is not present in the relied-upon references. Note further that the only place Bresnahan et al. mentions saline is in relation to inflating the occlusion balloon, not in any infusion context.

**Obviousness Rejections of Claims 5-8, 22-27, and 31-34 using Williams et al. in view and Loubser**

Turning to Claim 22, among other things, Claim 22 requires a "pump feeding heating/cooling agent at a flow rate in a range of 150 - 450 milliliters per minute *through the heat exchange element.*"

Considering the obviousness rejection of Claim 22 based on Williams et al. and Loubser, the relied-upon Loubser pump is not for inflating or circulating anything, but for one-way perfusion of drugs into the bloodstream. There is no suggestion that the relied-upon flow rate of the Loubser pump, or even the Loubser

1156-017.AP1

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 7

PATENT  
Filed: August 24, 2001

pump itself, is appropriate for circulating coolant into the cardioplegia balloon of Williams et al., because perfusion of drugs into the bloodstream for bypass surgery (the purpose of the Loubser pump) is an entirely different goal requiring entirely different flow considerations than circulating coolant into a cardioplegia balloon to measure cardiac output (Williams et al.)

In addition to the apples and oranges problem with the rejection, Appellant notes that Williams et al. nowhere discusses a particular coolant flow rate. The only place Williams et al appears to discuss flow rate at all is in the context of some hypothetical cardiac output calculations (blood flow rates) calculated by its cardioplegia system, col. 13, lines 24-33. There is thus no teaching or suggestion in any proffered reference that a cardiopulmonary bypass pump used for perfusion of substances into the blood is an appropriate instrument for circulating coolant into a cardioplegia balloon, much less that a pump flow rate for perfusing drugs into the blood during bypass surgery is a good flow rate to use for the entirely different purpose of coolant circulation performed to measure cardiac output by thermodilution.

The original brief observed that no mention had been made of the majority of the dependent claims, much less has it been identified where their respective limitations appear in the relied-upon references despite repeated chances on the part of the examiner to do so. The latest attempt to reopen prosecution is no less deficient. For instance, despite repeated requests to discuss why, precisely, the explicit and precise limitations of Claim 8 (injection caps), Claim 24 (temperature of the heating agent is between 38°C and 43°C), Claim 25 (temperature of the cooling agent is between 1°C and 5°C), Claim 27 (balloon length is about 55-60 mm), Claim 30 (three balloons disposed in a consecutive order with specific balloon diameters), Claim 31 (specific wall thickness), and Claim 33 (specific heat conductivity of balloon) are being rejected, these claims remain rejected without discussion, *after SPE review and approval of the present Office Action.*

1156 017 API

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 8

RECEIVED  
CENTRAL FAX CENTER


PATENT  
Filed: August 24, 2001

MAR 18 2008

Obviousness Rejections of Claims 5-8 and 22-34 using Bresnahan et al. and Loubser

Apropos the rejection based on Bresnahan et al. and Loubser, in both of the references the only pumps mentioned are for fluid infusion. No mention is made of any particular pump in Bresnahan et al. for inflating its occlusion balloon. So while the examiner is correct that Bresnahan et al. and Loubser both use pumps, he (and his SPE, who signed the latest Office Action) miss the point that even if Bresnahan et al. were to be modified per the Loubser pump, it would not be for inflating the relied-upon occlusion balloon of Bresnahan et al. (much less for cycling coolant through a heat exchange element as claimed), but for what both references teach about their pumps, namely, perfusion of substances for heart surgery.

Respectfully submitted,

  
\_\_\_\_\_  
John L. Rogitz  
Registration No. 33,549  
Attorney of Record  
750 B Street, Suite 3120  
San Diego, CA 92101  
Telephone: (619) 338-8075

JLR:jg

1156-017.AP1



**RECEIVED**  
**CENTRAL FAX CENTER****MAR 18 2008**CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 9**PATENT**  
Filed: August 24, 2001**APPENDIX A**

5. A central venous line catheter, said catheter having at least one substantially elongate structure configured for establishing central venous access, said structure having a proximal portion and a distal portion and defining at least a first lumen in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element extending at least along the distal portion adapted to effect heat exchange with the central venous system, characterized in that the catheter is manufactured by flushing the first lumen from its distal portion to its proximal portion with sterile saline.

6. The catheter of claim 5, characterized in that the volume of the flushing sterile saline is at least 5 ccm.

7. The catheter of claim 6, characterized in that a 5 ccm or larger syringe is used for flushing.

8. The catheter of claim 6, characterized in that injection caps are clamped to the proximal portion of the first lumen.

22. A venous line catheter system, said system having a catheter having at least one substantially elongate structure configured for establishing central venous access, said structure having a proximal portion and a distal portion and defining at least a first lumen in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element extending at least along the distal portion adapted to effect heat exchange with the central venous system, characterized by a pump feeding

1156-017.API

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 10

PATENT  
Filed: August 24, 2001

heating/cooling agent at a flow rate in a range of 150 – 450 milliliters per minute through the heat exchange element.

23. The catheter system of claim 22, characterized in that the flow rate is about 240 milliliters per minute.

24. The catheter system of claim 22, characterized in that the temperature of the heating agent is between 38°C and 43°C.

25. The catheter system of claim 22, characterized in that the temperature of the cooling agent is between 1°C and 5°C.

26. The catheter system of claim 22, characterized in that the heat exchanging element is a balloon.

27. The catheter system of claim 26, characterized in that the balloon length is about 55-60 mm.

28. The catheter system of claim 22, characterized in that the heat exchanging element comprises a plurality of balloons.

29. The catheter system of claim 28, characterized in that the balloon length is about 55-60 mm.

1156-017.AP1

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 11

PATENT  
Filed: August 24, 2001

30. The catheter system of claim 28, characterized in that three balloons are disposed in a consecutive order, a first balloon having a diameter of approximately 8-12 mm, a second balloon having a diameter of approximately 5-9 mm, and a third balloon having a diameter of approximately 4-6 mm.

31. The catheter system of claim 26, characterized in that the wall thickness of the balloon is between 35  $\mu\text{m}$  and 70  $\mu\text{m}$ .

32. The catheter system of claim 22, characterized in that the material from which the balloon is made is selected from the group: urethane, nylon, PE and PET.

33. The catheter system of claim 22, characterized in that the heat conductivity of the balloon is 0.1 to 1.5 Watt per meter  $\times$  Kelvin.

34. The catheter system of claim 22, characterized in that the heating/cooling agent is a sterile saline.

1156 017 API

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 12

**PATENT**  
Filed: August 24, 2001

**APPENDIX B - EVIDENCE**

None (this sheet made necessary by 69 Fed. Reg. 155 (August 2004), page 49978.)

1156 017.AP1

CASE NO.: 001/017  
Serial No.: 09/939,239  
March 18, 2008  
Page 13

**PATENT**  
Filed: August 24, 2001

**APPENDIX C - RELATED PROCEEDINGS**

None (this sheet made necessary by 69 Fed. Reg. 155 (August 2004), page 49978.)

11564(7.AP)